

## REMARKS

In the Office Action issued on June 5, 2008, the Examiner:

- objected to the specification;
- rejected claims 13, 17, and 21 through 27 under the second paragraph of 35 U.S.C. §112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicants regard as their invention;
- rejected Claims 13, 17 and 21 through 25 under 35 U.S.C. §102(b) as being anticipated by United States Patent No. 6,287,334 ("Moll"); and
- rejected Claims 26 and 27 under 35 U.S.C. §103(a) as being unpatentably obvious over Moll in view of United States Patent No. 6,669,724 ("Park").

The Applicants have fully considered the Office Action and cited references and submit this Reply and Amendment in response to the Examiner's action. Reconsideration of the application for patent is requested.

### Preliminary matter – Summary of Interview conducted on September 30, 2008

The undersigned attorney thanks the Examiner for the telephone interview held on September 30, 2008. In the interview, several of the amendments made herein to independent Claim 22 were discussed in comparison to Moll. Figures 13 through 16 of the current application were discussed as illustrating an example of the attachment pathway on the support structure that places the leaflets in a desirable coapting position in contrast to the minimum coaptation provided by Moll.

While no agreement with respect to the claims was reached, the Examiner's suggestions were helpful and have been fully considered as part of this Reply and

Amendment.

Amendments to the claims

The applicants have herein cancelled claims 13, 17, 21, and 23 through 27.

The Applicants have herein amended independent claim 22 as follows:

- to add "a vessel wall" in the preamble, for antecedent basis purposes;
- to remove the "at least" limitation on the first and second commissures;
- to indicate that the plurality of leaglets "is configured to" form a seal with the vessel wall and restrict fluid flow through the vessel, to avoid any belief that the vessel and/or vessel wall is being claimed as an element of the valve prosthesis;
- to change the "longitudinal" orientation of the proximal portion of the attachment pathway to one that is "substantially parallel" to the longitudinal axis of the support structure;
- to clarify that each leaflet of the plurality of leaflets has a coactable area and a basal portion;
- to further specify that the coactable area and basal portions of the leaflets are configured to cooperate with the vessel wall to define a valve pocket;
- to further specify that the coactable areas of the plurality of leaflets are configured to coapt with each other while said valve prosthesis is in a resting state; and
- to further specify that each coactable area of each leaflet of the plurality of leaflets has a length that is between 10% and 80% of the length of the valve prosthesis.

These amendments to claim 22 are made to more particularly point out and distinctly claim that which the applicants regard as the currently claimed

invention and to further distinguish the prior art references cited by the Examiner.

Each of the amendments is fully supported by the application as originally filed; no new matter has been introduced. Exemplary support is found in Figures 13 and 14, and in paragraphs [0042], [0045], [0046], and [0051].

The Applicants have also herein added new claims 30 through 32. These new claims read on the elected species and are fully supported by the original application as filed; no new matter has been introduced. Exemplary support is found in original claims 25 through 27, paragraphs [0042], [0046], and [0051], and in Figures 13 and 14.

#### Objection to the specification

The Examiner objected to the specification as failing to provide proper antecedent basis for the claimed subject matter. Specifically, the Examiner noted that the limitation in claim 22, "...the at least first and second...", has not been found in the specification.

The Applicants have herein amended claim 22 to eliminate the reference to "at least" with respect to the first and second commissures. The objection to the specification, therefore, is moot. The Applicants respectfully request its withdrawal.

#### Rejections under the first paragraph of 35 U.S.C. §112

The Examiner rejected claims 13, 17, and 21 through 27 under the second paragraph of 35 U.S.C. §112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicants regard as their invention. Each of these rejections is addressed individually below.

Regarding claim 13 and the "body passage" language, the applicants have herein cancelled claim 13. This rejection is, therefore, moot. The applicants respectfully request its withdrawal.

Regarding claim 13 and the "each of the plurality of leaflets is configured" language, the applicants have herein cancelled claim 13. This rejection is,

therefore, moot. The applicants respectfully request its withdrawal.

Regarding claim 17 and the pair of opposing leaflets language, the applicants have herein cancelled claim 17. This rejection is, therefore, moot. The applicants respectfully request its withdrawal.

Regarding claims 22 through 24 and the relationship between the first and second lateral edges and with respect to the leaflets, the applicants have herein cancelled claims 23 and 24. This rejection, with respect to these claims, is, therefore, moot. The applicants respectfully request its withdrawal.

Regarding the application of this rejection to claim 22, the applicants respectfully traverse this rejection of the claim because the claim language clearly indicates that the first and second lateral edges are portions of the leaflet outer edge:

“each leaflet of the plurality of leaflets having an outer edge *that includes* a first lateral edge extending distally from the first commissure and a second lateral edge extending distally from the second commissure”

No amendments to claim 22 have been made in response to this rejection. The applicants respectfully submit that the language is clear on its face and meets the requirements of §112. Withdrawal of this rejection of claim 22 is requested.

Regarding claim 17 and the longitudinal orientation language, the applicants have herein cancelled claim 17. This rejection is, therefore, moot. The applicants respectfully request its withdrawal.

#### Rejections under 35 U.S.C. §102

The Examiner rejected claims 13, 17 and 21 through 25 under 35 U.S.C. §102(b) as being anticipated by Moll. The Applicants have herein cancelled claims 13, 17, 21, and 23 through 25. The rejections of these claims are, therefore, moot and should be withdrawn.

As amended herein, claim 22 explicitly requires, among other limitations, that:

- the proximal portion of the attachment pathway along which the lateral edges of the leaflets are attached to the support structure comprise "a substantial portion of the length of the prosthesis";
- that the proximal portion of the attachment pathway have a "substantially parallel orientation with respect to the longitudinal axis of the [prosthesis] support structure"; and
- that the coaptable area of each leaflet of the plurality of leaflets has a length that is between 10% and 80% of the length of said valve prosthesis.

Moll does not anticipate independent claim 22 at least because it fails to teach any of these limitations of the claim. The proximal portion of the attachment pathway of the device taught by Moll cannot be said to have a "substantially parallel orientation" in relation to the longitudinal axis of the support structure. Even if a minimal proximal fragment of the attachment pathway (near the bends) is considered to have such an orientation, it cannot be said that such a portion comprise "a substantial portion of the length of the prosthesis."

The lack of a substantial portion of the attachment pathway oriented in this manner is evidenced by the lack of a coaptable area of the leaflets of the Moll device that has a length that is between 10% and 80% of the length of the valve prosthesis. In stark contrast to the extended coaptable area described in the current application and required by claim 22, the minimal coaptable area of the Moll device includes only the proximal edges of the leaflets (see Figures 1 and 6 of Moll, for example).

For at least these reasons, Moll does not, and cannot, anticipate claim 22 as amended herein. The applicants respectfully submit that this rejection of the claim has been over come and request its withdrawal.

### Rejections under 35 U.S.C. §103

The Examiner rejected Claims 26 and 27 under 35 U.S.C. §103(a) as being unpatentably obvious over Moll in view of Park. The Applicants have herein cancelled claims 26 and 27. The rejections of these claims are, therefore, moot and should be withdrawn.

### **CONCLUSION**

The Applicants have fully responded to the objections and rejections listed by the Examiner in the June 5, 2008, Office Action. A Notice of Allowability relating to all claims currently under consideration is appropriate and respectfully requested by the Applicants.

Should the Examiner have any questions regarding this Reply and Amendment, or the remarks contained herein, the undersigned attorney would welcome the opportunity to discuss such matters with the Examiner.

Respectfully submitted,

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